REMARKS/ARGUMENTS

Reconsideration of this application is requested. Claims 12, 14 and 15 remain active in the application subsequent to entry of this Amendment.

The title is amended responsive to the examiner's comments in item 1 of the Official Action.

Claim 13 has been canceled thereby rendering objections 2 and 3 moot. The remaining portions of the Official Action deal with prior art-based rejections all featuring the Floyd references WO 97/00681 and U.S. 5,492,510. The rejection was not made final for the reasons explained in item 9 of the Official Action.

Claim 12 is rejected under 35 USC §102(b, e) as being anticipated by the Floyd documents. Floyd discloses in column 2, lines 28 to 36, that "Further development of an injectable formulation has been hampered by the instability of lamotrigine itself in aqueous medium ..."

The solution to this problem proposed by Floyd was to make the mesylate salt of lamotrigine. Table 2 in Floyd reports the results of testing carried out employed lyophilized formulation containing lamotrigine mesylate not lamotrigine. Table 3 reports the results of tests carried out on the formulation as a reconstituted solution in sterile water. In neither instance is the stability to degradation of a pharmaceutical dosage form comprising lamotrigine tested.

It is, therefore, submitted that the present claims are not anticipated by Floyd.

In item 7 of the Official Action claim 15 is rejected as being "obvious" over the Floyd references and further in view of Papadoyannis. This rejection is respectfully traversed as the secondary reference does not secure the fundamental defects of the primary reference.

Floyd, as stated above, discloses that lamotrigine is unstable in aqueous solution. It does not disclose nor suggest that it may be beneficial to test the stability of solid

pharmaceutical dosage forms comprising lamotrigine for compound A[1]. The present application states that compound A can be formed by hydrolyzing lamotrigine under basic conditions. They hydrolysis is suitably conducted by combining lamotrigine and a base with water then heating. This concurs with Floyd's disclosure that lamotrigine in solution may be unstable.

There is no disclosure in Floyd that would suggest the solid pharmaceutical dosage forms may degrade in a similar manner and there is nothing in Floyd to suggest that the compound A would be a suitable reference marker in assaying pharmaceutical dosage forms.

The method disclosed in Papadoyannis used 3,5-diamino-6-(2-methoxyphenyl)-2,4-triazine, a different compound from compound A used in the present application as the internal standard. There is no disclosure in Papadoyannis of compound A. Papadoyannis provides no incentive to the skilled person to use compound A as an internal standard as the skilled person would not be motivated from the teaching in Floyd to think lamotrigine would degrade to compound A in solid pharmaceutical dosage forms. The present claims are inventive thereover.

In item 8 of the Official Action the examiner has added to the Floyd references Dreassi in combination with two additional documents. And, as before, the rejection is defective for the reasons previously stated.

Dreassi again uses 3,5-diamine-6-(2-methoxyphenyl)-1,2,4-triazine as an internal standard. Again there is no disclosure of compound A so Dreassi cannot add to the teaching of Floyd. The present claims are inventive thereof.

Qualia discusses the compound chlorothalidone and DeAngelis discusses the compound cinromide, both very different drugs to lamotrigine so neither reference can add anything to the disclosure of Floyd, because Floyd does not suggest that lamotrigine may degrade to compound A in solid pharmaceutical dosage forms. Qualia and

[1] 3-amino-6-(2,3-dichlorophenyl)-1,2,4-triazine-5-(4H)-one.

DeAngelis can in no way add to this teaching. The present claims are inventive thereover.

For the above reasons it is respectfully submitted that claims 12, 14 and 15 define patentable subject matter. Reconsideration and allowance are solicited.

Respectfully submitted,

NIXON & VANDERHYE P.C.

By: _____
Arthur R. Crawford
Reg. No. 25,327

ARC:eaw
1100 North Glebe Road, 8th Floor
Arlington, VA 22201-4714
Telephone: (703) 816-4000
Facsimile: (703) 816-4100